

DOCKET NO.: A0870.70000US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Collins et al.  
Serial No.: 10/783,020  
Confirmation No.: 3753  
Filed: February 23, 2004  
For: BIFIDOBACTERIUM IN THE TREATMENT OF  
INFLAMMATORY DISEASE  
Examiner: Vera Afremova  
Art Unit: 1651

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**CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)**

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 6<sup>th</sup> day of June, 2006.



Nicole M. Hawes

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**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed more than three months after the filing date of this application and after the mailing date of the first Office action, but before the mailing date of any final action under 37 C.F.R. §1.113, a Notice of Allowance under 37 C.F.R. §1.311, or an action that otherwise closes prosecution in this application.

The fee of \$180.00 as set forth in 37 C.F.R. §1.17(p) is enclosed.

**PART II: Information Cited**

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified PTO/SB/08). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

**PART III: Remarks**

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 (modified PTO/SB/08) be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

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Notwithstanding any statements by the Applicant, the Examiner is urged to form his or her own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,

By:

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Docket No.: A0870.70000US00  
Date: June 6, 2006  
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FORM PTO-1449/A and B (modified PTO/SB/08) <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/783,020	ATTY. DOCKET NO.: A0870.70000US00
				FILING DATE: February 23, 2004	CONFIRMATION NO.: 3753
				APPLICANT: Collins et al.	
				GROUP ART UNIT: 1651	EXAMINER: Vera Afremova
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#### U.S. PATENT DOCUMENTS

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	A1	4,347,240		Mutai et al.	08-31-1982
	A2	4,435,389		Mutai et al.	03-06-1984
	A3	5,032,399		Gorbach et al.	07-16-1991
	A4	5,443,826		Borody	08-22-1995
	A5	5,711,977		Yang et al.	01-27-1998
	A6	5,834,423		Koketsu et al.	11-10-1998
	A7	5,922,375		Luchansky et al.	07-13-1999
	A8	6,025,008		Akahoshi et al.	02-15-2000
	A9	6,077,504		Cavaliere ved. Vesley et al.	06-20-2000
	A10	6,132,710		Panigraphi et al.	10-17-2000
	A11	6,368,591		Chen et al.	04-09-2002
	A12	6,645,530		Borody	11-11-2003
	A13	2005-0214272	A1	Collins et al.	09-29-2005
	A14	2006-0002908	A1	Collins et al.	01-05-2006

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/Country	Number	Kind Code			
	B1	EP	0 384 319	B1	VISKASE CORPORATION	04-28-1999	
	B2	EP	0 508 701	B1	QUEST INTERNATIONAL B.V.	07-10-1996	
	B3	EP	0 904 784	A1	N.V. NUTRICIA	03-31-1999	
	B4	EP	1 312 667	A1	WAKAMOTO PHARMACEUTICAL CO., LTD.	05-21-2003	
	B5	GB	1 503 094		NISSHIN FLOUR MILLING CO. LTD.	03-08-1978	
	B6	JP	9241173		WAKAMOTO PHARMACEUT CO.	09-16-1997	Y-Abstract
	B7	RU	2 091 075	C1	GNII GENETIKI I SELEKTSII PROM	09-27-1997	Y-Abstract
	B8	RU	2 109 054	C1	MOSKOVSKJJ	04-20-1998	Y-Abstract
	B9	WO	89/05849	A1	CHR. HANSEN'S LABORATORIUM	06-29-1989	
	B10	WO	90/01335	A1	THOMAS BORODY	02-22-1990	

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<sup>#</sup> EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449/A and B (modified PTO/SB/08)				APPLICATION NO.: 10/783,020	ATTY. DOCKET NO.: A0870.70000US00
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	B11	WO	90/09398	A1	BIOINVENT INTERNATIONAL AB	08-23-1990	
	B12	WO	97/35596	A1	ABBOTT LABORATORIES	10-02-1997	
	B13	WO	98/00035	A1	CAVALIERE VED. VESELY	01-08-1998	
	B14	WO	98/35014	A2	FORBAIRT TRADINGS AS BIORESEARCH IRELAND	08-13-1998	
	B15	WO	99/51631	A1	KORHONEN	10-14-1999	
	B16	WO	99/62348	A1	ENTERPRISE IRELAND	12-09-1999	
	B17	WO	01/37865	A1	PROBIALL PTY LIMITED	05-31-2001	

#### OTHER ART – NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	C1	Adachi, Susumu, "Lactic Acid Bacteria and the Control of Tumours," The Lactic Acid Bacteria, 1:233-261, (1992).	
	C2	Anand et al., "Antibacterial Activity Associated with Bifidobacterium bifidum - II," Cult. Dairy Prod, pages 21-23, (1985). (Attached copy is missing 1 page)	
	C3	Arai et al., "Cytokines: Coordinators of Immune and Inflammatory Responses," Annual Rev. Biochem., 59:783-836, (1990).	
	C4	Aranda et al., "Analysis of Intestinal Lymphocytes in Mouse Colitis Mediated by Transfer of CD4 <sup>+</sup> , CD45RB <sup>high</sup> T Cells to SCID Recipients <sup>1</sup> ," Jour. of Immunology, 158(7):3464-3473, (1997).	
	C5	Arihara, et al., "Salivacin 140, a novel bacteriocin from Lactobacillus salivarius subsp. salicinius T140 active against pathogenic bacteria," Letters in Applied Microbiology, 22:420-424, (1996).	
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	C7	Blum et al., "Adhesion studies for probiotics: need for validation and refinement," Trends in Food Science & Technology, 10:405-410 (1999).	
	C8	Bouhnik et al., "Effects of Bifidobacterium sp fermented milk ingested with or without inulin on colonic bifidobacteria and enzymatic activities in healthy humans," Eur. Jour. Clin. Nut., 50:269-273, (1996).	
	C9	Bouhnik et al., "Survie et effets chez l'homme des bactéries ingérées dans less laits fermentés," LAIT, 73:241-247, (1993).	Y-Abstract
	C10	Brandtzaeg et al., "Immunopathology of human inflammatory bowel disease," Springer Semin Immunopath, 18:555-589, (1997).	
	C11	Brink et al., "Antimicrobial activity of lactobacilli: preliminary characterization and optimization of production of acidocin B a novel bacteriocin produced by Lactobacillus acidophilus M," Jour. of Applied Bacteriology, 77:140-148, (1994).	
	C12	Brzuszczak et al., "Cyclic AMP-dependent anion secretion in human small and large intestine," Jour. of Gastroenterology and Hepatology, 11:804-810, (1996).	

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	C13	Charteris et al., "Antibiotic susceptibility of potentially probiotic <i>Bifidobacterium</i> isolates from the human gastrointestinal tract," Letters in Applied Microbiology, 26:333-337, (1998).	
	C14	Charteris et al., "Selective detection, enumeration and identification of potentially probiotic <i>Lactobacillus</i> and <i>Bifidobacterium</i> species in mixed bacterial populations," Int. Jour. of Food Microbiology, 35:1-27, (1997).	
	C15	Charteris, et al., "Antibiotic Susceptibility of Potentially Probiotic <i>Lactobacillus</i> Species," Jour. Food Protection, 61(12):1636-1643, (1998).	
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	C20	Collins et al., "A Controlled Trial of Probiotic Treatment of IL-10 Knockout Mice," Gastroenterology, 116(4):1 page, (1999). Abstract G2981.	
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	C26	Collins et al., "Probiotic bacteria-interaction with the human immune system," Int. Congress and Symp. Series 219, pages 13-17, (1996).	
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	C29	Crabbe et al., "The Normal Microbial Flora as a Major Stimulus for Proliferation of Plasma Cells Synthesizing IgA in the Gut," Int. Arch. Allergy 34:362-375, (1968).	
	C30	Daly et al., "Biotechnology of lactic acid bacteria with special reference to bacteriophage resistance," Antonie Van Leeuwenhoek, 70:99-110, (1996).	
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	C33	Dekker et al., "Sensitive Pulsed Amperometric Detection of Free and Conjugated Bile Acids in Combination with Gradient Reversed-Phase HPLC," Chromatographia, 31(11/12):549-553, (1991).	
	C34	Dinarello et al., "New Concepts on the Pathogenesis of Fever," Reviews of Infectious Diseases, 10(1):168-189, (1988).	
	C35	Donnelly, et al., "Differential Regulation of IL-1 Production in Human Monocytes by IFN- $\gamma$ and IL-4," Journal of Immunology, 145(2):569-575, (1990).	
	C36	Dunne et al., "Epithelial Adhesion of Probiotic Microorganisms in vitro and in vivo," Gastroenterology, 116(4):1 page, (1999). Abstract G3058.	
	C37	Dunne et al., "Probiotics: from myth to reality. Demonstration of functionality in animal models of disease and in human clinical trials," Antonie Van Leeuwenhoek, XP000929178, 76:279-292, (1999).	
	C38	Favier et al., "Fecal $\beta$ -D-Galactosidase Production and Bifidobacteria Are Decreased in Crohn's Disease," Digestive Diseases and Sci., 42(4):817-822, (1997).	
	C39	Feeney et al., "Lack of Specific Systemic Immune Response on Oral Consumption of Probiotic Lactobacilli," Int. Dairy Journal, 8(5/6):1 page, (1998).	
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	C41	Flynn et al., "Isolation and Characterisation of the Novel Anitbacterial Proteins, ABP-1 and ABP-118 from Human Isolates Lactobacillus salivarius subsp. salivarius UCC-1 and UCC-118," Intl. Dairy Jour., 8(5/6):1 page, (1998).	
	C42	Fuller, "Probiotics in man and animals," Jour. of Applied Bacteriology, 66:365-378, (1989).	
	C43	Gahan et al., "Innate resistance to Listeria monocytogenes in tumor-bearing mice," Jour. of Leukocyte Biology, 62:726-732, (1997).	
	C44	Ganguly et al., "Mechanism of action of cholera toxin & other toxins," Indian J. Med. Res., 104:28-37, (1996).	
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	C47	Gardiner et al., "Evaluation of Cheddar Cheese as a Food Carrier for Delivery of a Probiotic Strain to the Gastrointestinal Tract," J. Dairy Sci., 82:1379-1387, (1999).	
	C48	Gardiner et al., "Influence of a Probiotic Adjunct Culture of Enterococcus faecium on the Quality of Cheddar Cheese," J. Agric. Food Chem., 47:4907-4916, (1999).	
	C49	Gardiner et al., "Preparation of Spray Dried Powders Harbouring High Levels of Probiotic Lactobacilli," Sixth Symp. on Lactic Acid Bacteria, Abstract J29, (1999).	
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	C52	Gibson, Glenn, "Dietary modulation of the human gut microflora using prebiotics," Jour. of Nutrition, 80(2):S209-S212, (1998).	
	C53	Gilliland, Stanley, "Health and nutritional benefits from lactic acid bacteria," FEMS Microbiology Reviews, 87:175-188, (1990).	
	C54	Gionchetti et al., "Microflora in the IBD Pathogenesis: Possible Therapeutic Use of Probiotics" Gastroenterology Intl., 11(1):108-110, (1998).	
	C55	Groot, J.A., "Correlation between electrophysiological phenomena and transport of macromolecules in intestinal epithelium," The Veterinary Quarterly, 20(3):S45-S49, (1998).	
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	C57	Henderson et al., "Cytokines, homeostasis, networks and disease," Bacteria-Cytokine Interactions in Health and Disease, pages 79-130, (1998).	
	C58	Houde et al., "Treatment of Acute Enteritis with Oral Administration of Short-Term High-Dose Bifidobacteria," Chinese Jour of Microecology, 6(6):47, (1994). Y	Y
	C59	Huis et al., "Establishing a scientific basis for probiotic R&D," 12:6-8, (1994).	
	C60	Inagaki et al., "Causes of Death in Cancer Patients," Cancer, 33(2):568-573, (1974).	
	C61	Isolauri et al., "Oral Bacteriotherapy for Viral Gastroenteritis," Digestive Diseases and Sciences, 39(12):2595-2600, (1994).	
	C62	Jinggang, Lan, "Immunopotentiating Activity of Bifidobacterium and Its Significance," For. Med. Sci., Clinic Biochem & Med Test, 19(5):231-233, (1998). Y	Y
	C63	Jong, S.C., "Probiotics for Humans and Animals," ATCC Quarterly Newsletter, 13(1):1-4, (1993).	
	C64	Kagnoff, "Immunology of the Intestinal Tract," Gastroenterology, 105:1275-1280, (1993).	
	C65	Kato et al., "Suppressive Effects of the Oral Administration of Lactobacillus Casei on Type II Collagen-Induced Arthritis in DBA/1 Mice," Life Sciences, 63(8):635-644, (1998).	
	C66	Kawakami et al., "A Group of Bactericidal Factors Conserved by Vertebrates For More Than 300 Million Years," Journal of Immunology, 132(5):2578-2581, (1984).	
	C67	Kim et al., "The Properties of Bifidobacteria Isolated from Korean," Korean Journal of Dairy Science, 20(3):191-204, (1998). Y-Abstract	Y-Abstract
	C68	Kim, Hyung, "Characterization of Lactobacilli and Bifidobacteria as applied to Dietary Adjuncts <sup>1</sup> ," Cultured Dairy Products Journal, pages 6-9, (1988).	
	C69	Klaenhammer, Todd, "Genetics of bacteriocins produced by lactic acid bacteria," FEMS Microbiology Rev., 12:39-86, (1993).	
	C70	Kühn, et al., "Interleukin-10-Deficient Mice Develop Chronic Enterocolitis," Cell, 75:263-274, (1993).	
	C71	Kulkarni et al., "Inhibitory Effect of Bifidobacterium longum Cultures on the Azoxymethane-Induced Aberrant Crypt Foci Formation and Fecal Bacterial $\beta$ -Glucuronidase," Proc. Soc. Experim. Biol. Med., 207:278-283, (1994).	

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C72	Lamm et al., "Interaction of antigens and antibodies at mucosal surfaces," Ann Rev Microbiol, 51:311-40, (1997). (Previously cited as Ramos et al.)	
C73	Lee et al., "The coming of age of probiotics," Trends in Food Science & Technology," 6:241-245, (1995).	
C74	Legrand-Defretin et al., "Ion-Pair High-Performance Liquid Chromatography of Bile Salt Conjugates: Application to Pig Bile," LIPIDS, 26(8):578-583, (1991).	
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C76	Lucey et al., "Developing Fields in Food Biotechnology," Food Science and Technology, 11(4):230-233, (1997).	
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C80	Marteau et al., "Potential of using lactic acid bacteria for therapy and immunomodulation in man," FEMS Microbiology Reviews, 12:207-220, (1993).	
C81	Mattila-Sandholm, "Novel Methods for Probiotic Research," Demonstration Project Fair2 CT96-1028, Pages 11-15, (1997).	
C82	Mattila-Sandholm, et al., "Probiotics: towards demonstrating efficacy," Trends in Food Sci & Tech., 10:393-399, (1999).	
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C84	McCracken, et al., "Probiotics and the Immune System," Probiotics a Critical Review, pages 85-113, (1999).	
C85	McFarland, et al., "Pharmaceutical Probiotics for the Treatment of Anaerobic and Other Infections," Anaerobe, 3:73-78 (1997).	
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C87	Medaglini et al., "Mucosal and systemic immune responses to a recombinant protein expressed on the surface of the oral commensal bacterium <i>Streptococcus gordonii</i> after oral colonization," Proc. Natl. Acad. Sci, 92:6868-6872, (1995).	
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